In the communication dated December 28, 2000, the examiner stated that the above-identified application failed to comply with the Sequence Listing requirements of 37 C.F.R. 1.821-1.825 for failing to provide an initial computer readable "Sequence Listing" and a paper copy of the "Sequence Listing". However, the Patent Office has determined that a Sequence Listing was not required for the parent of the present application and, therefore, under the relevant rules a Sequence Listing is not required for the present application (see Exhibit A).

REMARKS

A. Under M.P.E.P. 2421.01 - A Sequence Listing is Not Required for the Present Application

The applicants respectfully submit that according to M.P.E.P. 2421.01, in effect as of the filing of the parent of the present application, a Sequence Listing for the present case is not required because the application is not a "new application".

> Section 2421.01 says in pertinent part:
>
> Compliance [with sequence listing requirements] is required for most disclosures of sequence data in *new applications filed on or after October 1, 1990.*
>
> --For PCT application, the filing date must be on or before October 1, 1990, and the U.S. must be one of the designated states and **the U.S. must be the International Searching Authority and/or the International Preliminary Examining Authority**... (Emphasis aded)

The present application is a divisional application of U.S. patent application seriel no. 08/484,893 which was a continuation of U.S. patent application serial no. 07/971,857, now U.S. Patent No. 5,969,108 (the '108 patent), which was the U.S. national stage of PCT/GB91/01134 (the '01134 patent). The UK Patent Office was the International Preliminary Examining Authority and the European Patent Office was the International Searching Authority for the '01134 patent, and thus the present application (a continuation of the '108 patent) does not fall within the definition of a "new application" under M.P.E.P. 2421.01. The Patent Office agreed with the applicants' assertion that a Sequence Listing was not required for the application giving rise to the '108 patent noting that the U.S. was neither the International Searching

Authority nor the International Preliminary Examining Authority (see Exhibit A -- Decision on Petition). For that reason, the applicants submit that a Sequence Listing is not required for the present application.

B. Article 27(1) PCT Prohibits National Law Requiring Compliance With Requirements Relating to the Form or Contents of the International Application Different From or Additional to Those Which Are Provided for in the PCT

An international application has an international and a national phase and then may mature into a patent. This is clear from Article 3 PCT and from Articles 23(1) and Article 40(1) PCT which refer to the designated or elected Offices (see Article 2(xiii) and (xiv) PCT for definitions) examining an international application. The national patent offices only examine international applications in the national phase. (There should be a clear distinction from the situation wherein a national patent office acts as an International Searching Authority or International Preliminary Examining Authority.) 35 U.S.C. 375 and MPEP 1896 also refer to a [US] patent issuing on an international application. See also the PCT Applicant's Guide at paragraph 11 (copy enclosed).

Furthermore, note the discussion in the MPEP at 1801 of Basic PCT Principles, in particular the reference to the ability of an "applicant to file one application, "an international application", in a standardized format". That is a major *raison d'etre* of the PCT. A single application, in a standardized format, undergoes formalities examination (by the Receiving Office), is searched (by the International Searching Authority), published (by the International Bureau) and may be examined substantively in a preliminary manner (by the International Preliminary Examining Authority), in the international phase, before entering the national phase, at which time the national Offices examine the application for substantive patentability according to national law. Article 27(5) PCT allows each Contracting State to apply its own substantive conditions of patentability, but Article 27(1) PCT prohibits national law requiring "compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in [the PCT]". Again, it is stressed that national law has no bearing whatsoever on the international phase of an application under the PCT, so Article 27(1) must (i.e., can only) apply to the national phase.

This is borne out by paragraph 25 of the PCT Applicant's Guide (copy enclosed) and, indeed, MPEP 1815, which says "International Applications which comply with the PCT formal requirements are acceptable by all PCT member states (Article 27(1) PCT)".

A limited number of exceptions to Article 27 are provided by Rule 51bis, but there is no mention of sequence listings, formal drawings, etc. The exceptions listed in Rule 51bis are the only exceptions.

Thus, since the parent of the present application was filed under PCT before Rule 5.2, PCT came into force requiring the description of an international application to contain a formal Sequence Listing complying with the standard prescribed by the Administrative Instructions, the Examiner cannot require the furnishing of a Sequence Listing. US law is subservient to the PCT in this respect.

There are other cases where international applications in the US national phase are treated differently from regular US national applications with respect to form and contents, because of Article 27 (1) PCT. One example is the difference in requirements for unity of invention and restriction practice. For a regular national application 37 CFR 1.141 applies (note the reference in this rule to a "national application"). However, this rule and the practice associated with it differs from the requirements of Rule 13 of the Regulations under the PCT. Because of Article 27(1), a separate rule must be applied under US national law to the US national phase of PCT applications. That rule is 37 CFR 1.499, which explicitly refers to Rule 13 PCT. In other words, PCT Rule 13 (arising from PCT Article 3(4)(iii) is governing.

As set out in the attached Decision on Petition (Exhibit A) issued in connection with the parent part of this application, the Patent Office agreed that the PCT application upon which the parent of the present application was based predated the 1992 change in the PCT rules requiring compliance with the sequence rules and that a Sequence Listing was not required. On that basis, the applicants respectfully submit that a Sequence Listing is not required for the present application.

C. Conclusion

Because the above-identified application is not a "new application" as defined by M.P.E.P. 2421.01, and because a Sequence Listing requirement for the above-identified application is prohibited by Article 27(1) of the PCT, the applicants respectfully submit that the requirement is improper and should be withdrawn.

Respectfully submitted,

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March 27, 2001

EXHIBIT A

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Paper No. 17

MARSHALL O'TOOLE
MAILED: December 27, 1994

In re application of
John McCafferty et al.
Serial No. 07/971,857
For: METHODS FOR PRODUCING MEMBERS OF SPECIFIC BINDING PAIRS : Decision on Petition

Applicants have filed a petition for supervisory intervention under the provisions of 37 CFR 1.181, dated October 21, 1994, with regards to the examiner's refusal to consider applicants' letter of August 19, 1994 to be a bona fide response to the outstanding requirement. The outstanding requirement, issued August 1, 1994, indicated that applicants had failed to comply with the Sequence Rule requirements in that they had failed to file the compilation of disclosed sequences in electronic form.

Applicants' response directed the examiner to the appropriate section of the MPEP and argued that, since the instant application was filed under 35 USC 371 and was based upon an International Application in which the UK Patent Office served as both the International Preliminary Examining Authority and the International Searching Authority, compliance with the Sequence Rules was not required. It is further noted that the PCT application, upon which the instant application is based, predated the 1992 change in the PCT Rules requiring compliance with the Sequence Rules.

Upon a thorough consideration of the facts and applicants' arguments, I find that the examiner erred in requiring applicants to comply with the Sequence Rules for the reasons succinctly discussed by applicants in the petition. Accordingly, the petition is granted and the application has been forwarded to the examiner for initiation of the examination process in due course. Additionally, since the petition for supervisory intervention did not require the payment of a fee therefor, arrangements have been made for the crediting of the $130.00 petition fee to applicants' Deposit Account No. 13-2855.

PETITION GRANTED

Barry S. Richman, Director
Patent Examining Group 1800
Biotechnology

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